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To Whom It May Concern:

I am writing in response to the FDA proposal to regulate allograft tissue. I hope that the regulations will not increase the cost of providing a much needed product. I hope that the FDA regulations will not lead to the decreased supply of bone products because of multiple regulations and requirements that may be added to the handling of such products. There are a great deal of safety concerns that have been addressed in the past. There have been little if any side effects, especially in my practice related to the use of banked bone. Without appropriate documentation, I do not foresee a need for the FDA's need to regulate allograft tissue. Patients greatly depend on allograft tissue. It cuts down the cost of hospitalization, surgery and, therefore, the overall health care costs.

If you have any questions about this, please do not hesitate to call or write.

Best Regards,



Dan E. Miulli, D.O., F.A.C.O.S.

DEM:djr

dr: 11/30/99/TSI39024

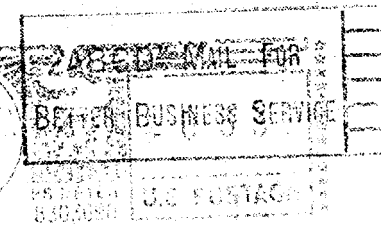
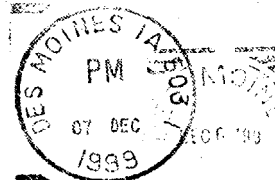
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